K033534

11.0 510(K) SUMMARY

11.1 Summary information

11.1.1 Submitter's name and address

Jack E. McKenzie, Ph.D.
Mini-Mitter Co., Inc.
20300 Empire Ave., Bldg. B-3
Bend, Oregon 97701
541-322-7272
Fax 541-322-7277

Date summary was prepared: November 4, 2003

11.1.2 Name of device

Trade Name:	*VitalSense®*
Common Name:	Physiological Data Logging Device
Classification Name:	Physiological Signal Conditioner
Product Code:	GWK

11.1.3 Identification of predicate device

Mini-Logger® Series 2000, Physiological Data Logging Device

510(k) Number : K991045

11.1.4 Device description

11.1.4.1 Functions of the device

VitalSense® is a compact, ambulatory, physiological data logger. *VitalSense®* may be attached to the belt or worn in a shirt pocket. Up to ten telemetric sensors may be used with a single *VitalSense®* logger. The device senses and records physiological data and displays the data on its LCD screen. Recorded data may be transferred later to a PC for display and conversion for export to other programs.

11.1.4.2 Basic scientific concepts

The device acquires and logs digital data whose values represent the amplitudes of physiological signals. Currently available wireless sensors (see Addendum 1) sense temperature as the physiological signal. The scientific concepts and technologies that are used to sense the signals are summarized in Table 13.

TABLE 13. BASIC TECHNOLOGIES USED FOR PHYSIOLOGICAL SIGNAL RECORDING IN *VITALSENSE®* SENSORS

Physiological Parameter	Sensor Used	Sensor Technology	Signal Obtained
Skin surface temperature	Surface dermal patch	Thermistor resistance varies uniquely with temperature.	Digital waveform whose duty cycle represents temperature.
Core body temperature	Ingestible capsule	Thermistor resistance varies uniquely with temperature.	Digital waveform whose duty cycle represents temperature.

11.1.4.3 Physical characteristics

Pertinent physical characteristics of the *VitalSense®* data logger are shown in Table 14.

TABLE 14. PHYSICAL CHARACTERISTICS OF *VITALSENSE®* LOGGER

Parameter	Value
Size	120 x 90 x 25 mm
Weight	200 grams
Battery type	3.6 volt lithium cell (1 ea)
Case material	Polycarbonate/ABS plastic
Moisture protection	IEC529-IP52 NEMA250-5
Storage temperature	-20 C to 50 C at 5-95% relative humidity
Operating temperature	0 C to 40 C
Interface panel	Non-permeable membrane switch panel
Display	Monochrome liquid-crystal with backlight

11.1.5 Statement of the intended use of the device.

VitalSense® can be used in any setting where physiological body core and skin temperature are used to further the understanding of body function. The device can be used for simultaneous assessment of core body temperature, dermal surface temperature, or ambient temperatures that require logging of data over time with subsequent conversion, display, and analysis of the aforementioned parameters. *VitalSense®* may be used in any instance where quantifiable analysis of temperature data is desirable.

11.1.6 How the technological characteristics of the device compare to those of the predicate device

VitalSense® and the *Mini-Logger® Series 2000* (FDA 510(k) Number: K991045) are each diagnostic test systems based upon the concept of an ambulatory, unattended physiological logger that logs sensor-input physiological data to the logging device. The device communicates

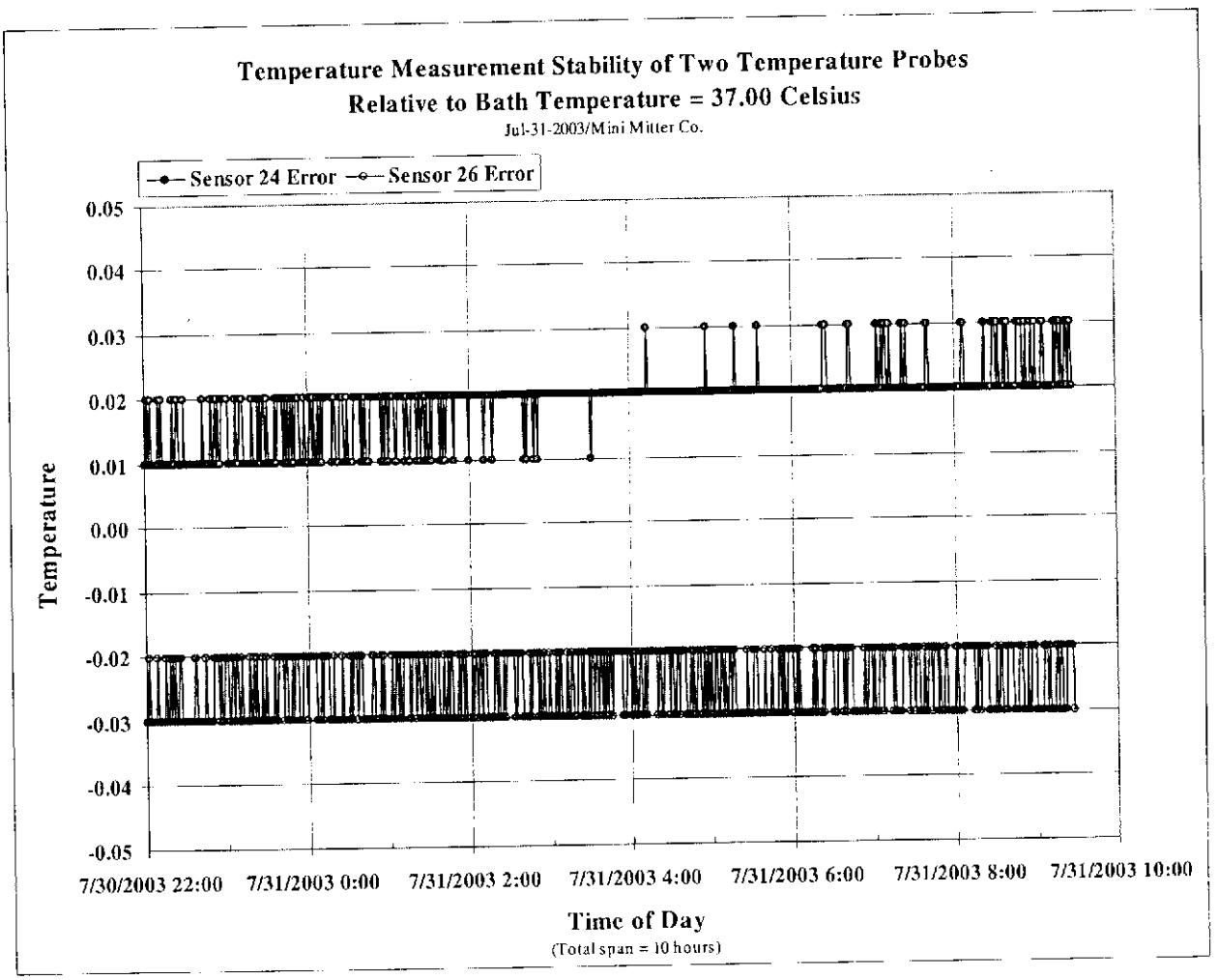
the data with an IBM compatible personal computer (PC). Each of these devices is a solid-state logger with data collection algorithms, definable numbers of channels, types of channels, and with the ability to store data until it is downloaded into the PC. *VitalSense®* and the *Mini-Logger® Series 2000* are of similar size and weight. Both devices have an internal clock and event marker to time-stamp and mark data for later interpretation. *VitalSense®* has the potential to input specific types of data on each of ten channels. The *Mini-Logger® Series 2000* has the potential for five sensor inputs.

11.2 Assessment of non-clinical performance data

Mini Mitter Company has verified the performance of the *VitalSense®* data logger using a *Design Inputs* ⇔ *Design Outputs* methodology. Of the tests conducted in this verification, the temperature stability and temperature linearity are the two most important performance considerations. Mini Mitter Company has established criteria for the stability of temperature measurements, based on *ASTM-E1112-00, clause 4.2*. A summary of the test results for those are provided below.

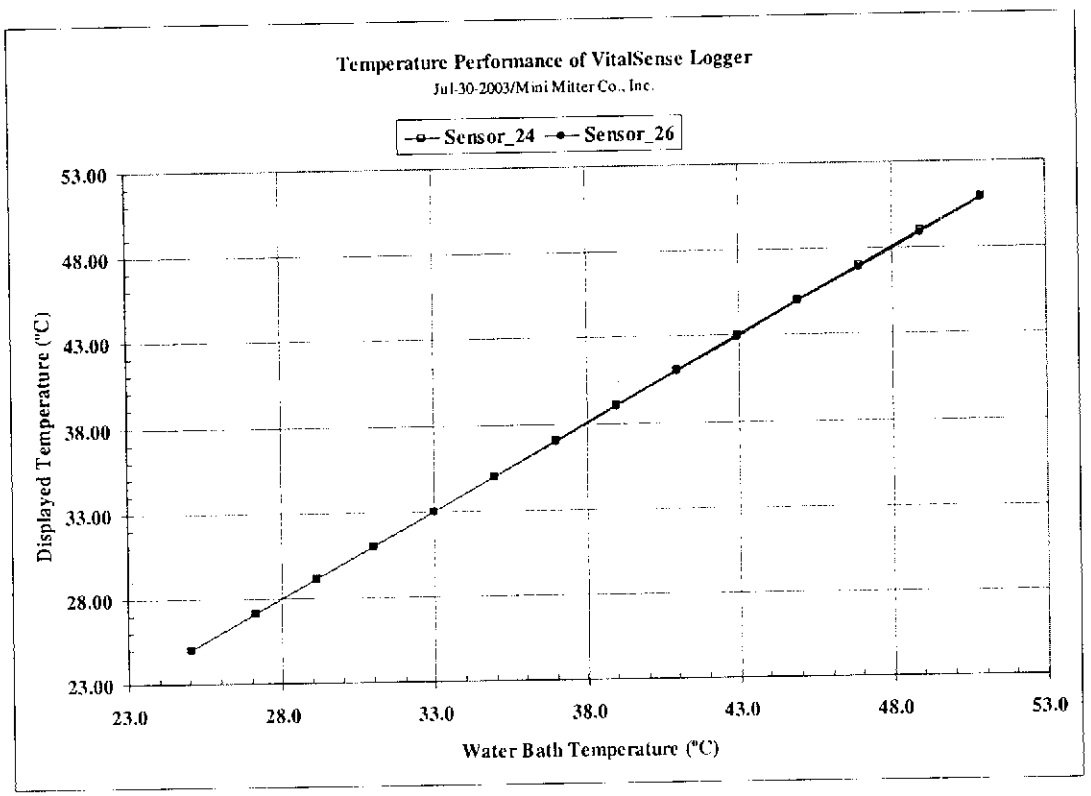
11.2.1 First test: stability of temperature measurement

The measured temperature must not drift more than +/- 0.1 °C over a 10- to 12-hour period. As the chart indicates, the stability is +/- 0.01 °C, ten times better than required.



11.2.2 Second test: temperature linearity

The measured temperature must agree to within +/- 0.1 °C of a standard, NIST-traceable digital RTD thermometer. Mini Mitter has tested the accuracy of *VitalSense®* over the range 25 – 50 Celsius, and its performance is within +/- 0.1 °C (see section 5.6). See following chart.



11.3 Comparison to predicate device performance

Comparable data for the predicate device appear in the 510(k) Premarket Notification for that device (submitted June 22, 1999, by Mini Mitter Co., Inc.). In that Notification, data were provided that demonstrate *Mini-Logger® Series 2000* has a typical accuracy of +/- 0.08 °C and a stability of +/- 0.03 °C. Data provided in the present Premarket Notification for *VitalSense®* demonstrate a typical accuracy of +/- 0.05 °C and a stability of +/- 0.01 °C. Thus, *VitalSense®* performance exceeds that of the currently-marketed predicate device. A summary of these results appears in Table 12.

TABLE 12. *VITALSENSE®* AND *MINI-LOGGER®* SERIES 2000, TEMPERATURE MEASUREMENT CHARACTERISTICS

Figure of Merit	***VitalSense®***	***Mini-Logger® Series 2000***
Typical Accuracy	+/- 0.05 °C	+/- 0.08 °C
Typical Stability	+/- 0.01 °C	+/- 0.03 °C

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 2 2004

Mini Mitter Company, Inc.
Jack E. McKenzie, Ph.D.
20300 Empire Avenues
Building B-3
Bend, Oregon 97701

Re: K033534
Trade/Device Name: VitalSense
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: January 22, 2004
Received: February 11, 2004

Dear Dr. McKenzie:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K033534

Device Name: VitalSense® Integrated Physiological Monitoring System

Indications For Use:

VitalSense® can be used in any setting where physiological body core and skin temperature are used to further the understanding of body function. The device can be used for simultaneous assessment of core body temperature, dermal surface temperature, or ambient temperatures that require logging of data over time with subsequent conversion, display, and analysis of the aforementioned parameters. *VitalSense®* may be used in any instance where quantifiable analysis of temperature data is desirable.

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K033534

Prescription Use __x____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)